35-Day Full-thickness Wound Healing Study of MAP Wound Matrix in Diabetic Yucatan Miniature Swine

Donald R. Griffin PhD[1,2], Stephanie Deshayes PhD[1], and Westbrook M. Weaver PhD[1].

[1]Tempo Therapeutics, Inc., San Diego, CA, [2]Biomedical Engineering, Chemical Engineering, University of Virginia, Charlottesville, VA.

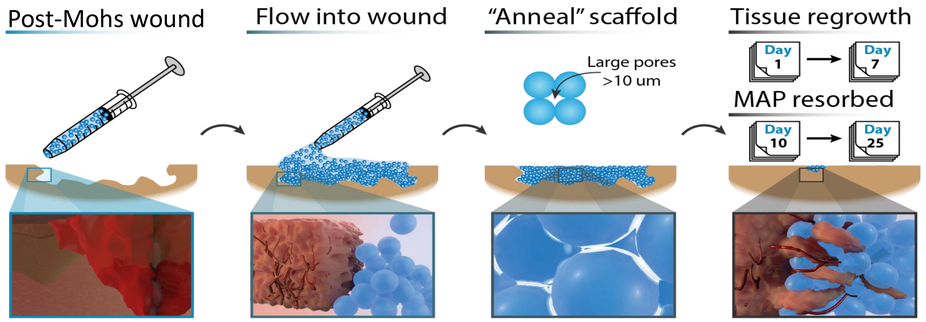
Introduction

The Clinical Challenge in Diabetic Foot Ulcers

- More than 38 million Americans have diabetes (> 9% of the US population).
- ~25% of diabetic patients will develop diabetic foot ulcers (DFUs) in their lifetime (~8 millions in US alone).
- Only 30% of DFUs heal within 12 weeks. More than 500k complex surgical resection are performed each year.
- An estimated 20% of DFU patients require lower limb amputation.
- Patients with DFU have a 5-year patient mortality rate of 74%.
- These statistics outline a clear need for innovative wound care materials that can accelerate healing and improve outcomes.

MAP Wound Matrix, a Revolutionizing Scaffold

Microporous **A**nnealed **P**article (**MAP**) **Wound Matrix** is a 'smart' flowable and resorbable wound matrix with a unique porous microenvironment that enables rapid tissue integration without eliciting a foreign body response. The MAP Wound Matrix enables, with a single application, a new treatment for wounds of any shape without the use of cells, biologics or growth factors.



MAP Wound Matrix is delivered to the wound as a flowable concentrated hydrogel microsphere solution, and then, upon white light exposure, is transitioned *in situ* to a robust scaffold. The resultant scaffold displays a functional open pore structure with microscale porosity (pore size: 10 - 50 µm) to allow free movement of cells to build new tissue prior to enzymatically mediated material resorption.

- **Flowable**
- **Any wound shape**
- **Single application**
- **No cells, no biologics, no growth factors, no animal-derived products**
- **No foreign body response**
- **Synthetic matrix**
- **Rapid tissue integration**
- **Bioresorbable**

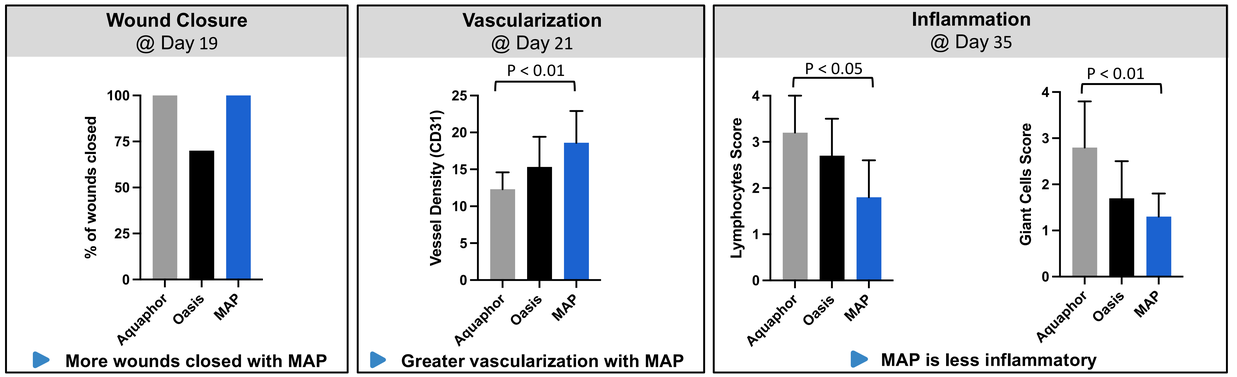
Objective of the Study

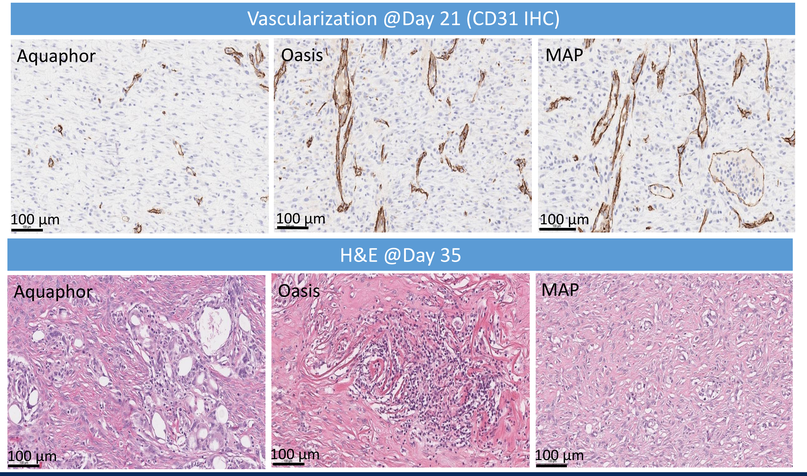
The purpose of this study was to evaluate the efficacy of the MAP Wound Matrix, a novel biomaterial, as a single application treatment to promote diabetic wound healing using a diabetic porcine model.

Methods

Twelve full-thickness wounds (2 x 2 cm) were created on the back of each alloxan-induced diabetic Yucatan miniature swine. Wounds were treated with either MAP Wound Matrix (referred as MAP), Aquaphor (standard of care), or Oasis SIS (comparator). Animals were followed for up to 35 days. This study measured the histological wound healing characteristics as primary endpoints including re-epithelialization, inflammation, vascularization, and device degradation. The study also measured clinical wound observations as secondary endpoints, such as skin reactions, and wound closure.

Results





Conclusion

The MAP Wound Matrix holds promise as an alternative therapeutic option for DFUs, including the promotion of multiple superior wound healing outcomes relative to current clinical options. Importantly, the scaffold's ability to act as a single treatment option that reduces the need for repeated clinician intervention suggests that it may improve patient outcomes and reduce healthcare burden. Further clinical studies will validate its efficacy and safety in patients.

References

1. D.R. Griffin, *et al*, *Nature Materials*, ***2015*** 14: 737–744.
2. D.R. Griffin, *et al*, *Nature Materials*, ***2021*** 20: 560–569.

deshayes@tempothera.com
Website: http://tempothera.com/